
III. DISEASE PREVENTION THROUGH VACCINE DEVELOPMENT AND IMMUNIZATION

Prevention of infectious diseases through the development of new or improved vaccines and their use in immunization programs is a multifaceted process, as illustrated in figure 1. Surveillance provides accurate information on the incidence and distribution of disease, and that information informs policy makers and the public about threats to health and thereby helps guide the setting of priorities for vaccine development and immunization efforts. To be useful in planning, surveillance must include the capability for early detection of new, expanding, and reemerging infections (Institute of Medicine, 1992). In the case of diseases for which no vaccines yet exist, biomedical research must first be conducted to understand how protection might be accomplished. Vaccine candidates are then developed, usually by vaccine companies, through applied research, including process development and scale up, with subsequent testing for safety and protective efficacy. The next step is licensing, with prospective manufacturers seeking licenses for effective vaccines if they believe there is a commercially viable market for such products.¹

Immunization efforts proceed once the supply of a licensed vaccine is ensured. Immunization entails a number of steps, including vaccine purchase or procurement, distribution, and administration by providers to the target recipients. The effectiveness of such immunization efforts can be measured by determining "vaccination coverage" (the proportion of the target population that is properly vaccinated) -- which is dependent on the health care infrastructure, access to and cost of vaccination services, and acceptance by health care providers and the public -- and ultimately the reduced occurrence of the disease is detected through surveillance.

The vaccine development and immunization process necessarily involves many active participants, including vaccine recipients (and for children, their surrogate decision makers); health care providers and payers; vaccine companies; Federal, State, and local government agencies; and international organizations. The roles of these contributors to the process are summarized in figure 2.

The actual rate of progress made in disease prevention through vaccine development and immunization is governed by four main factors. These factors are:

- the "demand" for control of the disease, that is, the perceived public health threat and the expected benefits of control;
- the scientific feasibility of making the desired vaccine and the demonstration of its safety and effectiveness;
- the perceived existence of a commercially viable market for the vaccine, which determines whether a potential producer will develop, seek licensure for, and manufacture the needed product; and
- a commitment to the effective use of the vaccine by public health and political decision makers, as well as provision of the human and financial resources necessary to achieve effective use.

¹In the United States, nearly all vaccines are made by commercial vaccine companies. In addition, two States, Massachusetts and Michigan, hold vaccine licenses and have a limited-volume production capacity.